

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/932,172	TWARDZIK ET AL.	
	Examiner Stephen Gucker	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to \_\_\_\_.
2.  The allowed claim(s) is/are 1-2, 9-10, 15-16, renumbered as 1-6, respectively.
3.  The drawings filed on \_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 10/21/02
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_.
7.  Examiner's Amendment/Comment same document
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_.

**EXAMINER'S AMENDMENT & REASONS FOR ALLOWANCE**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa A. Haile on 6/25/04.

An examiner's amendment to the record appears below.

In the specification:

Page 1, line 2, inserted after "August 17, 2000":

--now abandoned--. ✓

Page 1, line 4, inserted after "August 19, 1999":

--now abandoned--. ✓

Page 27, line 12, inserted after "(the disclosure of which is incorporated by reference herein)":

--now abandoned--. ✓

In the claims:

Canceled claims 3-8 and 11-14. ✓

Amended the following claims:

1. (Currently Amended) A method for expanding a subject's population of insulin-producing cells, for a subject in need of such treatment, comprising administering a composition consisting essentially of an effective amount of [a TGF- $\alpha$  polypeptide (SEQ ID NO:1), a TGF- $\alpha$ -related polypeptide,] a TGF- $\alpha$ 57 polypeptide (SEQ ID NO:3)[, a fragment thereof, or a mimetic thereof].

2. (Currently amended) The method of claim 1, wherein the [TGF- $\alpha$  polypeptide, TGF- $\alpha$ -related polypeptide,] TGF- $\alpha$ 57 polypeptide[, fragment thereof, or mimetic thereof] is pegylated.

10. (Currently amended) A method for treating Type I [or Type II] diabetes comprising administering a composition consisting essentially of an effective amount of TGF- $\alpha$ 57 polypeptide (SEQ ID NO:3) [a combination consisting of:

- a) a TGF- $\alpha$  polypeptide (SEQ ID NO:1), a fragment thereof, or a mimetic thereof; and
- b) a TGF- $\alpha$ -related polypeptide].

2. The following is an examiner's statement of reasons for allowance: the closest prior art of record is US 5,885,956 (Nardi et al., "Nardi", reference AL on PTO-1449). Nardi teaches a method comprising the administration of TGF- $\alpha$  and gastrin to stimulate pancreatic islet cell neogenesis and to treat diabetes mellitus (Type I diabetes). Nardi does not teach or reasonably suggest the use of the specific TGF- $\alpha$ -related polypeptide TGF- $\alpha$ 57 (SEQ ID NO:3) to expand a population of insulin-producing cells or to treat Type I diabetes. The instant claims employ the transitional phrase "consisting essentially of" to emphasize the exclusion of the use of TGF- $\alpha$  alone, or in combination with gastrin, or the use of TGF- $\alpha$ 57 (SEQ ID NO:3) in combination with gastrin, from what is encompassed by the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

*SG*

Stephen Gucker

June 28, 2004

*Gary d. Kunz*  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600